

been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 423.1092 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 423.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in 423.858.

Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review

SOURCE: 74 FR 65363, Dec. 9, 2009, unless otherwise noted.

§ 423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs, and the MAC with respect to reopenings.

(b) ALJs with respect to hearings.

(c) MAC with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings, MAC reviews, and judicial review by a Federal District Court.

§ 423.1970 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy* (1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.1972(b); and

(iii) The ALJ determines that the appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.1972(b); and

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(iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription.

§ 423.1972 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request.* Except when an ALJ extends the timeframe as provided in § 423.2014(d), the enrollee must file a request for a hearing within 60 calendar days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 423.2020 of this chapter.

(c) *Insufficient amount in controversy.* (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.1970, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.1970, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.1974 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal as provided in § 423.2102.

§ 423.1976 Judicial review.

(a) *Review of ALJ's decision.* The enrollee may request judicial review of an ALJ's decision if—

(1) The MAC denied the enrollee's request for review; and

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision.* The enrollee may request judicial review of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review.* In order to request judicial review, an en-

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rollee must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. (See § 423.2136 for a description of the procedures to follow in requesting judicial review.)

§ 423.1978 Reopening determinations and decisions.

(a) A coverage determination or redetermination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or the MAC that is otherwise binding may be reopened and revised by the entity that made the determination or decision as provided in § 423.1980 through § 423.1986.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638 of this chapter.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

§ 423.1980 Reopenings of coverage determinations, redeterminations, reconsiderations, hearings and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. Consistent with § 423.1978(a), that action may be taken by—

(i) A Part D plan sponsor to revise the coverage determination or redetermination;

(ii) An IRE to revise the reconsideration;

(iii) An ALJ to revise the hearing decision; or

(iv) The MAC to revise the hearing or review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, hearing, or MAC review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all